School of Pharmaceutical Sciences & Technology

Curriculum for

Fellowship Program in

REGULATORY TOXICOLOGY

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Course Title: REGULATORY TOXICOLOGY
Course Type: FELLOWSHIP
Duration: 360 Hours (can be structured as 24 Credits)
Mode: Lectures, Practicals/Hands-on, Project

Overview

The Fellowship in Regulatory Toxicology is an intensive, short-term postgraduate program designed for the safety of drugs, biologics, medical devices, cosmetics, pesticides, and food additives to ensure they meet regulatory requirements before approval for human use or environmental release**.** The primary purpose is to safeguard human health and the environment by discovering, analysing, and controlling harmful risks using scientific evidence.

Objectives:

Upon completion of the course, the fellow shall be able to:

- To understand laws pertaining to drug discovery and development.
- To analyse hazards and risks associated with substances.
- To assist Regulatory filings for national and international standards .
- Basic understanding of regulatory guidelines and authorities.

Course Outcome:

CO No.	Course Outcome
CO1	Explain the drug discovery, development its regulations and registrations.
CO2	Analyze and apply animal experimentations, dose caliculations,cell culture techniques and general toxicological studies.
CO3	To apply knowledge on clinical trail phase development studies,regulatory bodies and its authorities for drug approval process.
CO4	To learn technology transfer process,its documentation and facilitate the commercialization of research, bridging public R&D labs and private industries

Teaching & Learning Methods:

The program emphasizes a documentation -based approach. This includes interactive lectures with case studies, mandatory computer lab sessions using experimental software, webinars and talks by industry experts, assignments and quizzes for evaluation, and discussion forums for collaboration.

Syllabus

Theory - 10 Credits (150 Lecture Hours)

Module 1: Introduction to Regulatory Toxicology (45 hours)

- Drug discovery and development: Drug Laws, FDA, OECD, ICH

- Schedule Y: Design non-clinical toxicity studies and clinical development.
- Drug discovery and registration: Regulatory affairs, WTO, patent regime, accreditation and harmonization.
- Models and bioassay: Methods in toxicity testing,dose-responsecharacterization
- Regulations of human pharmaceuticals: Preclinical development. Regulation for biological products.Future of drug safety.

Module 2: Pharmacology and Toxicology (45 hours)

- Introduction to pharmacological research, Research ethics and publication ethics.
- Animal experimentation: Advantages and disadvantages; Anaesthesia used in laboratory animals, common agents, dose calculations, cannulation methodology, ventilation rate, recording of arterial blood pressure, intestinal motility etc
- Animal cell-culture techniques: Aseptic handling, cell counting and cell viability assays. Tissue isolation, tissue fixation, common fixatives, preparation of single cell suspension.
- Introduction to general toxicology,History, Classification and ramification in toxicology
- Human health risk assessment, Hazard identification, Risk prediction and management.

Module 3: Technology development / transfer (30 hours):

- Drug related technology development; Toxicological studies, bioequivalence (BU).
- clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies;
- Scale-up, semi-commercialisation and commercialisation-practical aspects and problems
- Significance of transfer of technology (TOT), technology transfer management,-guidelines for research students, scientists and related personal.

Module 4: commercialisation related aspects (30 hours):

- TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI
- TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsary licensing excess to medicine issues.
- DOHAdeclaration, POSTWTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalisation of IP; Drug registration and licensing issues-national and global.

Practical/Hands-on Component: 8 Credits (120 Lab Hours)

1.Fundamentals of Computers(15 hours):

- Introduction to computers, basic unit and functions
- H/W and S/W, operating systems, word processing, spread sheet, graphic programs, dbase.
- windows, statistical S/W programs

2. Computer Applications in Pharmaceutical Sciences (30 hours):

- Hands on experience in pharmaceutical software systems
- Hands on experience in animal software systems
- Use of computers in information retrieval systems

3. Toxicity Classification & Labelling (45 hours):

- Preparation of hazard labels and safety symbols.
- Interpretation of **LD_{50} values**.
- Prepare regulatory toxicology documentation.
- Understand OECD, ICH, US FDA, EMA, and CDSCO guidelines.
- Dose selection, observation parameters, and outcome interpretation

4. Risk Assessment & Risk Management **(30 hours):**

- Hazard identification and dose–response assessment.
- Human health risk assessment case study

Project: 6 Credits (90 Self Study/Research Hours):

A mandatory Project (6 credits) provides practical application. Projects typically involve familiarization on regulatory guidelines,Regulatory acceptance criteria, Regulatory requirements asp er ICH S5(R3), Weight-of-evidence approach in regulatory submissions, OECD Toxicology Guidelines. Toxicological information section drafting.

References:

1. Shayne C. Gad Taylor & Francis Regulatory Toxicology
2. A. Wallace Hayes Principles and Methods of Toxicology
3. Karen Stine, Thomas M. Brown Principles of Toxicology
4. Casarett & Doull's Essentials of Toxicology, edited by CD Klassen and JB Watkins.
5. Goodman & Gilman The Pharmacological Basis of Therapeutics .
6. CPCSEA guidelines http://cpcsea.nic.in
7. Bansal PR Handbook for Pharma Students and Researchers

8. Hopkins AL. Network pharmacology: the next paradigm in drug discovery. *Nat Chem Biol*. 2008.
9. Barabási AL, Gulbahce N, Loscalzo J. Network medicine: a network-based approach to human disease. *Nat Rev Genet*. 2011.
10. David Jacobson-Kram & Kit A. Keller T**oxicology study design, regulatory testing requirements, and data interpretation** for regulatory acceptance.
11. R. N. Gupta Handbook of Regulatory Affairs in India
12. OECD Test Guidelines Manual https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/test-guidelines.html .